

Remarks

Claims 11, 21, 23, 126-128, 131, 133 and 134 are cancelled without prejudice or disclaimer.

Claims 1, 9, 20, 22, 26 and 136 are amended. Support for the amendments to claims 1 and 136 can be found in the specification at least on page 4 lines 13-14, page 5 lines 16-22 and 27-29, page 8 lines 2-7 (which states that in one embodiment a cytokine can be administered, thereby supporting that in other embodiments a cytokine is not administered) and lines 10-11, page 9 lines 3-10, and page 51 lines 17-20, and in claims 126-128 as previously pending.

Support for the amendments to claim 9 can be found in the specification at least on pages 46-47.

Support for the amendments to claim 26 can be found throughout the specification and in claim 1 as originally filed.

New claims 137-146 have been added. Support for these claims can be found in the specification at least on page 3 lines 24-30, page 4 lines 1-3, page 5 lines 16-26, page 7 lines 24-29, page 8 lines 1-7, 10-11 and 17-18, and in claims 1, 20, 135 and 136 as previously pending.

No new matter has been added.

Claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135 and 136 and new claims 137-146 are pending, with previously pending claims 1 and 136 and new claims 137-139 and 141 being independent claims.

Applicant reserves the right to pursue the subject matter of the originally filed claims in continuing applications.

Applicant acknowledges withdrawal of the rejections under 35 U.S.C. §102(e) in view of Hutcherson or Agrawal. Applicant further acknowledges withdrawal of the rejections under 35 U.S.C. §103(a) in view of Briles et al. (U.S. Patent No. 6,042,838) and various other references.

Information Disclosure Statements

Applicant thanks the Examiner for the return of the previously submitted PTO Form 1449s. However, Applicant notes that it is not clear if the Examiner has considered all of the references (e.g., US 2004-0115219, WO01/17551, Klinman et al., Moss et al., Pisetsky et al., etc.). Applicant requests clearer indication of the Examiner's consideration of every reference contained in the PTO-Form 1449.

Claim Objections

Claim 9 is objected to partly because “derivatives of cholera toxin” is recited twice. Applicant has amended the claim to delete one of these recitations. Claim 9 is further objected to because, according to the Examiner, the terms “MLP”, “MDP”, “MF59”, “SAF”, “PROVAX”, and “PCPP” should be spelled out in full. Although these terms are understood in the art in their abbreviated form, Applicant has complied with this request for the sake of expediting prosecution.

Reconsideration and withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. §112

Written Description

Claims 131 and 133-134 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Without conceding to the Examiner’s position and rather in the interest of expediting prosecution, Applicant herewith cancels claims 131 and 133-134. Accordingly, withdrawal of this rejection is respectfully requested. Applicant reserves the right to pursue the subject matter of these cancelled claims in continuing applications.

Enablement

Claims 131 and 133-134 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. According to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Without conceding to the Examiner’s position and rather in the interest of expediting prosecution, Applicant herewith cancels claims 131 and 133-134. Accordingly, withdrawal of this rejection is respectfully requested. Applicant reserves the right to pursue the subject matter of these cancelled claims in continuing applications.

Indefiniteness

Claims 9, 22 and 26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 9 has been amended to delete reference to “such as”.

Claim 22 has been amended to replace “derived” with “obtained” as suggested by the Examiner. Although Applicant considers the term “derived from” to be understood in the art, this amendment is made in the interest of expediting prosecution.

Claim 26 has been amended to replace “immunity” with “immune response”.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102

U.S. Patent No. 6,218,371 B1 (Krieg '371)

Claims 1, 4-9, 11-13, 15-23, 26-28, 126-129 and 135-136 are rejected under 35 U.S.C. §102(e) as being anticipated by Krieg '371 as evidenced by McCluskie et al. (Vaccine).

Without conceding to the Examiner's position and rather in the interest of expediting prosecution, Applicant has amended claims 1 and 136 to recite that a cytokine is not administered to the subject. Support for this amendment can be found in the specification at least on page 8 lines 3-4, and in claim 24 as originally filed. These passages and claim state that in one embodiment a cytokine can be administered, thereby supporting that in other embodiments a cytokine is not administered. Krieg '371 requires the administration of a cytokine and therefore the reference does not anticipate the pending claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

U.S. Patent No. 6,239,116 B1 (Krieg '116)

Claims 1, 4, 8-9, 11-13, 15-23, 26 and 135136 are rejected under 35 U.S.C. §102(e) as being anticipated by Krieg '116 as evidenced by McCluskie et al. (Vaccine).

Claims 1 and 136 have been amended to recite particular routes of administration of oligonucleotide and antigen. Support for this amendment can be found in the specification at

least on page 5 lines 13-21. These administration routes are not taught in Krieg '371, and therefore the reference does not anticipate the pending claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103

U.S. Patent No. 6,218,371 B1 (Krieg '371) in view of U.S. Patent No. 6,689,757 (Craig)

Claims 1 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Krieg '371 in view of Craig as evidenced by McCluskie et al. (Vaccine).

Without conceding to the Examiner's position and rather in the interest of expediting prosecution, Applicant has amended claim 1 to recite that a cytokine is not administered to the subject. Krieg '371 requires administration of an immunopotentiating cytokine with the CpG oligonucleotide. The combination of references requires, *inter alia*, cytokine administration to a subject. The pending claims exclude this possibility. Therefore the combination of references does not render obvious the pending claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

U.S. Patent No. 6,607,732 (Morein) in view of Krieg '116

Claims 1, 4-6, 8-9, 11-12, 15-23, 26-28, 126-129, 135 and 136 are rejected under 35 U.S.C. §103(a) as being unpatentable over Morein et al. in view of Krieg '116.

Without conceding to the Examiner's position and rather in the interest of expediting prosecution, Applicant has amended claims 1 and 136 to recite that an ISCOM is not administered to the subject. Morein teaches a composition that comprises an ISCOM. The combination of references requires, *inter alia*, the presence of an ISCOM. The pending claims exclude this possibility. Therefore the combination of references does not render obvious the pending claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Double Patenting Rejection

Claims 1 and 136 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 145 of co-pending Application No. 10/888,886.

Applicant defers any further rebuttal of this rejection until it becomes final. In doing so, Applicant is not conceding the propriety of any of the Examiner's statements with respect to the cited and the present claims.

Conclusion

A favorable action is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance and prior to the issuance of a further action.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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